IN THE UNITED STATES DISTRICT COURT
FOR THE EASTERN DISTRICT OF TENNESSEE

CHILDREN'S HEALTH DEFENSE, *et al.*, *Plaintiffs*, v. FOOD & DRUG ADMINISTRATION, *et al.*, *Defendants*.	Case No. 1:21-cv-00200-CLC-CHS

MEMORANDUM IN OPPOSITION TO PLAINTIFFS' MOTION FOR A STAY AND IN SUPPORT OF DEFENDANTS' MOTION TO DISMISS

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

RULES

REGULATIONS

OTHER AUTHORITIES

INTRODUCTION

In the midst of a pandemic, Plaintiffs ask this Court to make a safe and effective vaccine illegal. Contending that the Food and Drug Administration ("FDA") cannot both license Pfizer Inc.'s and BioNTech Manufacturing Gmbh's[1] Comirnaty vaccine and continue an Emergency Use Authorization ("EUA") for the Pfizer-BioNTech vaccine, Plaintiffs demand vacatur of *both* the license *and* the EUA. *See* Am. Compl., ECF No. 19, at 12. But the Court need not reach the merits of Plaintiffs' claim because the Court lacks jurisdiction. Even if this Court had jurisdiction, Plaintiffs fail to state a claim upon which relief may be granted. The Court should therefore dismiss the case and decline Plaintiffs' request to "stay" the Comirnaty license.

First, the Court lacks subject matter jurisdiction because Plaintiffs have no standing. Neither Plaintiff alleges a personal injury. Indeed, except for a vague, conclusory assertion of unspecified "imminent harm," Amy Miller alleges no injury at all. Implicitly invoking a theory of associational standing, Children's Health Defense ("CHD") points to military service members who speculate about possible injuries from a vaccine mandate imposed by a federal agency *that CHD has not sued* and that may impose the same mandate even if CHD prevails. These allegations fail to give CHD associational standing for two reasons: (1) Plaintiffs do not identify a CHD member who would have standing to sue in his or her own right, and (2) the interests of the

[1] Both the licensed Comirnaty vaccine and the EUA-authorized Pfizer-BioNTech COVID-19 vaccine are jointly sponsored by Pfizer Inc. and BioNTech Manufacturing Gmbh. For ease of reference, this brief will refer to both companies simply as "Pfizer."

adult military members that CHD purportedly seeks to protect are unrelated to CHD's mission of preventing childhood epidemics.

Second, Plaintiffs fail to state a claim on which relief may be granted. To the extent that they challenge the Pfizer-BioNTech EUA, they fail to state a cognizable claim because "emergency-use authorizations are exempt from review under the APA." *Ass'n of Am. Physicians & Surgeons v. FDA ("AAPS I")*, No. 20-1784, 2020 WL 5745974, at *3 (6th Cir. Sept. 24, 2020). In any event, their contention that approval of the Comirnaty vaccine required revocation of the Pfizer-BioNTech EUA is contrary to the text of the relevant statute because (1) the conditions that justified original issuance of the EUA continue to exist and (2) even if they did not, the statute expressly makes revocation permissive, not mandatory. Finally, Plaintiffs' assertions that FDA's approval of the license and maintenance of the EUA violated the requirement of reasoned decisionmaking are implausible and do not identify any relevant factor that FDA failed to consider. The case should be dismissed.

STATUTORY AND REGULATORY BACKGROUND

Section 351 of the Public Health Service Act prohibits introducing a biological product—including a vaccine—into interstate commerce without a license. 42 U.S.C. §§ 262(a)(1)(A), (i)(1). FDA reviews and approves an application for licensure on the basis of a demonstration that (1) the vaccine is "safe, pure, and potent," (2) "the facility in which the [vaccine] is [produced] meets standards designed to assure that the vaccine continues to be safe, pure, and potent," and (3) the applicant consents to inspection of the manufacturing facility. *Id.* § 262(a)(2)(C).

In addition, the Federal Food, Drug, and Cosmetic Act recognizes an exception for products distributed under an EUA. *See* 21 U.S.C. § 360bbb-3(a)(1). The Secretary of Health and Human Services (acting through FDA's Commissioner, *id.* § 393(d)(2)) may issue an EUA for an unlicensed vaccine if he declares a public emergency arising from a "disease or condition" attributable to a virus, *id.* §§ 360bbb-3(a)(1), (a)(2), (b)(1)(C), and finds that certain conditions are met, including "that there is no adequate, approved, and available alternative to the product for diagnosing, preventing, or treating such disease or condition," *id.* § 360bbb-3(c)(3). If later those conditions "are no longer met," the Secretary "*may* revise or revoke an authorization." *Id.* § 360bbb-3(g)(2) (emphasis added). The Secretary's decisions under this authority "are committed to agency discretion." *Id.* § 360bbb-3(i).

FACTUAL AND PROCEDURAL BACKGROUND

On January 31, 2020, the Secretary declared the COVID-19 pandemic to be a public health emergency. Am. Compl. ¶ 12. About two months later, the Secretary declared that the public health emergency qualified the authorization of drugs, medical devices, and biological products for emergency use. *Emergency Use Authorization Declaration*, 85 Fed. Reg. 18250 (Apr. 1, 2020). Citing that emergency, FDA issued an EUA on December 11, 2020, for the Pfizer-BioNTech COVID-19 vaccine to be administered to individuals 16 years of age and older. Am. Compl. ¶ 15. Since then, FDA has extended that authorization to children as young as 12 years old and issued similar EUAs for COVID-19 vaccines made by Moderna and Johnson & Johnson. *Id.* ¶ 19; Am. Compl., Exhibits, ECF No. 19-1, Ex 4, at 4.

On August 23, 2021, FDA approved a license for Pfizer's Comirnaty vaccine for use in individuals 16 years of age and older. Am. Compl. ¶ 20. In a letter to Pfizer dated the same day and attached to Plaintiffs' Amended Complaint, FDA both "clarif[ied] that the EUA will remain in place for the Pfizer-BioNTech COVID-19 vaccine for the previously-authorized indication and uses" and "authoriz[ed] use of [the Comirnaty vaccine] under [the] EUA for certain uses that are not included in the approved [license]." ECF No. 19-1, Ex. 3, at 2. In so doing, FDA noted that the Comirnaty and the Pfizer-BioNTech vaccines have the same formulation and may be used interchangeably to provide the vaccination series without presenting any safety or effectiveness concerns, although they are legally distinct. *Id.*, at 2 n.8. For example, whereas licensed vaccines are subject to the labeling requirements of 21 C.F.R. § 201.56, the EUA statute does not impose the same requirements on EUA-authorized vaccines. *Cf.* 21 U.S.C. § 360bbb-3(e)(1)(A). Also, a licensed vaccine may be made only at facilities approved as part of the license application. *See* 42 U.S.C. § 262(a)(2)(C)(i)(II). That same day, FDA denied a CHD petition urging FDA to revoke all EUAs for COVID-19 vaccines and not license a COVID-19 vaccine. ECF No. 19-1, Ex. 4.

On August 31, 2021, Plaintiffs filed their Complaint in this Court. On September 9, Plaintiffs filed an *ex parte* application and a motion for a "stay" of the Comirnaty vaccine license. This Court construed the *ex parte* application as a request for a temporary restraining order, and denied that request because Plaintiffs had failed to show irreparable harm. *See* Order, ECF No. 10, at 3-5 (Sept. 10, 2021). The Court also construed Plaintiffs' motion for a "stay" as a motion for a preliminary injunction, and

deferred deciding that motion until Defendants had a chance to be heard. *Id.* Pursuant to the scheduling order entered by this Court, ECF No. 13, Plaintiffs filed their amended motion for a "stay" on September 17. ECF No. 14, 18. They then filed their Amended Complaint on September 23. ECF No. 19.

STANDARDS OF REVIEW

To survive a motion to dismiss for lack of subject matter jurisdiction, *see* Fed. R. Civ. P. 12(b)(1), or failure to state a claim, *see* Fed. R. Civ. P. 12(b)(6), a plaintiff's complaint must contain "plausible" factual allegations that, taken as true, establish subject matter jurisdiction and the plaintiff's entitlement to relief. *Ass'n of Am. Physicians & Surgeons v. FDA ("AAPS II")*, 13 F.4th 531, 544 (6th Cir. 2021). A plaintiff cannot rest on "labels and conclusions," but must set forth "[f]actual allegations" that "raise a right to relief above the speculative level." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 555 (2007); *see also Ashcroft v. Iqbal*, 556 U.S. 662, 678-79 (2009). That standard governs a plaintiff's obligation to plead standing, as well as its obligation to plead its claim for relief. *AAPS II*, 13 F.4th at 544.

"A preliminary injunction is an extraordinary remedy which should be granted only if the movant carries his or her burden of proving that the circumstances clearly demand it." *Overstreet v. Lexington-Fayette Urb. Cty. Gov't*, 305 F.3d 566, 573 (6th Cir. 2002). A plaintiff must show (1) a substantial likelihood of success on the merits, (2) irreparable injury, (3) a balance of equities in the plaintiff's favor, and (4) that the public interest would be served by an injunction. *Liberty Coins, LLC v. Goodman*, 748 F.3d 682, 689-90 (6th Cir. 2014); *accord Winter v. Nat. Res. Def. Council, Inc.*, 555 U.S. 7, 20 (2008); *see*

also Nken v. Holder, 556 U.S. 418, 434 (2009) (applying same standards to stay request). As part of the first factor, the plaintiff must make a showing of a "substantial likelihood" of standing. *Memphis A. Philip Randolph Inst. v. Hargett*, 978 F.3d 378, 386 (6th Cir. 2020); *Waskul v. Washtenaw Cnty. Cmty. Mental Health*, 900 F.3d 250, 256 n.4 (6th Cir. 2018).

ARGUMENT

I. Plaintiffs Lack Article III Standing.

As a threshold matter, this Court should dismiss the case for lack of subject matter jurisdiction because Plaintiffs lack standing. To have standing, "a plaintiff must show (i) that he suffered an injury in fact that is concrete, particularized, and actual or imminent; (ii) that the injury was likely caused by the defendant; and (iii) that the injury would likely be redressed by judicial relief." *TransUnion LLC v. Ramirez*, 141 S. Ct. 2190, 2203 (2021). As a general rule, a plaintiff may assert only his or her own injuries. *See AAPS II*, 13 F.4th at 539; *see also Hollingsworth v. Perry*, 570 U.S. 693, 710 (2013). And although the requirement of an injury-in-fact may be satisfied by "threatened injury," that injury must be "certainly impending" to support standing. *Clapper v. Amnesty Int'l. USA*, 568 U.S. 398, 401 (2013).

Here, however, Plaintiffs plead no injuries to themselves. CHD does not claim to have been injured. And Amy Miller alleges only that she "is at imminent risk of immediate harm" without alleging *how* she will be harmed. Am. Compl. ¶ 5. "Such conclusory allegations are too speculative to support an actual injury, let alone one that

was certainly impending." *Thomas v. TOMS King (Ohio), LLC*, 997 F.3d 629, 639 (6th Cir. 2021).[2]

Rather than assert their own injuries, Plaintiffs appear to rely on a theory that CHD has associational standing to assert the rights of its members. Am. Compl. ¶ 4 (alleging that CHD sues "on behalf of its members who have been affected by Defendants' actions."). Under the doctrine of associational standing, an organization can "sue on behalf of its members if it shows that: (1) its 'members would otherwise have standing to sue in their own right'; (2) the 'interests' that the suit 'seeks to protect are germane to the organization's purpose'; and (3) 'neither the claim asserted nor the relief requested requires the participation of individual members in the lawsuit.'" *AAPS II*, 13 F.4th at 537 (quoting *Hunt v. Washington State Apple Advert. Comm'n*, 432 U.S. 333, 343 (1977)). CHD, however, fails to plead facts establishing either the first or second requirements.

A. CHD does not identify a member with standing.

In an apparent effort to meet the first requirement of associational standing, CHD submitted fifteen declarations in which the declarants, whom Plaintiffs allege are CHD members,[3] assert various injuries. *See* ECF No. 15. Even assuming these

[2] Because Amy Miller's claims are the only potential basis for venue in this District, *see* Am. Compl. ¶ 10, and Amy Miller lacks standing, the Court may dismiss this case for improper venue without reaching CHD's standing. *See* 28 U.S.C. § 1406(a); Fed. R. Civ. P. 12(b)(3).

[3] While one of the declarants—the one who asserts no injuries of her own—alleges that she is a "writer" for CHD, Long Decl. ¶ 4, none of the declarants claim to be CHD members.

declarations are properly incorporated by reference into the Amended Complaint, *see* Am. Compl. ¶ 18, they are not sufficient to identify a member of CHD who would have standing to sue in his or her own right. First, the declarations do not establish that any of the alleged CHD members have suffered or imminently will suffer a concrete and particularized injury. Second, even if the declarations established some Article III injury, they do not show that any injury is fairly traceable to Defendants' conduct (as opposed to the conduct of the non-party Department of Defense). And third, Plaintiffs likewise fail to show that any alleged injuries are likely to be redressed by the judicial relief sought.

1. CHD fails to plead, let alone show, that any of its members can meet the injury-in-fact requirement. As this Court has already explained, CHD's original declarant, Pam Long, claims no injury to herself and does not identify any service members referred to in her declaration as CHD members. *See* Order, ECF No. 10, at 3, 5. The remaining fourteen declarants allege that the Department of Defense has required them to get vaccinated or face adverse consequences, including loss of benefits, discharge, and court-martial. *See, e.g.*, Craymer Decl. ¶¶ 7, 11. Some allege that they have experienced unwanted testing, masking requirements, vague forms of social pressure and "ridicule," and restrictions on their training and duties. *See, e.g.*, Craymer Decl. ¶¶ 8, 11; Eschmann Decl. ¶ 8. They also allege that, given FDA's determination that Comirnaty and the EUA vaccine can be used interchangeably to provide the vaccination series without presenting safety and effectiveness concerns, they may be required to receive the EUA vaccine. *See, e.g.*, Craymer Decl. ¶ 12. Most of the declarants

also allege that they are "concerned" about side effects of the vaccine if they do take it. *See, e.g.*, Eschmann Decl. ¶ 11. But their vague and conclusory allegations do not establish an actual or "certainly impending" injury. *See Thomas*, 997 F.3d at 639.

To begin with, it is purely speculative at this point whether the declarants will be required to take an EUA-authorized vaccine. Eleven declarants allege that they have requested or will request religious or medical exemptions, and *none* alleges that his or her request has been denied.[4] Two other declarants do not make any claim that they are required to take an EUA-authorized vaccine to which they object.[5] The remaining declarant alleges that his commanders have somehow ignored his religious exemption, but he does not say whether he complied with an order to bring documentation of his exemption to the vaccination site. Perez Decl. ¶ 7. Moreover, the declarants only

[4] *See* Craymer Decl. ¶ 7 (declarant has "written a religious exemption"); Eschmann Decl. ¶ 7 ("I have filed a religious exemption but have not heard the results …."); Hastriter Decl. ¶ 7 (declarant's exemptions "have not been denied yet"); Hollowell Decl. ¶ 6 (declarant will be injured "if" exemption denied); Mason Decl. ¶¶ 7-8 (declarant may claim exemption upon return from leave); Meachan Decl. ¶ 7 (declarant "plan[s]" to request exemption); Nuss Decl. ¶ 7 (declarant has "been told" by unidentified persons that exemption will be denied); Raethel Decl. ¶ 7 ("I am currently pursuing a religious exemption …."); Santos Decl. ¶ 7 ("I have initiated a religious accommodation request …. The process is still ongoing."); Sweger Decl. ¶ 7 ("I have submitted a request for religious exemption and am waiting for it to be routed up the chain of command."); Am. Zito Decl. ¶ 7 ("I intend to submit my religious exemption ….").

[5] *See* Shour Decl. ¶¶ 5, 7 (declarant has not made "any final decision" about vaccination); Stanzione Decl. ¶¶ 5-7 (declarant has refused to get the vaccine "thus far" because of "the current non-availability of the FDA licensed vaccine" at his post, but has been told that the licensed vaccine is available off-site).

speculate that the licensed vaccine will be unavailable before declarants face any adverse action.[6]

In addition, none of the declarants claim to be likely to suffer an injury from a vaccine. At most, some of the declarants express vague "concern" about fertility and other issues. *See* Eschmann Decl. ¶ 11. But any "contention that they will be uniquely harmed from vaccines that, according to the CDC, more than 200 million people ha[ve] received . . . , is specious." *Robert v. Austin*, 21-cv-2228, ECF No. 12, at 5 (D. Colo. Sept. 1, 2021).

2. Even if the declarations establish some actual or imminent Article III injuries, they do not establish that those injuries are "fairly traceable" to *Defendants'* alleged conduct. At most, the alleged injuries arise from a vaccine mandate imposed *by the Department of Defense*. But CHD "did not sue [the Department of Defense]. It sued the FDA." *AAPS II*, 13 F.4th at 546. FDA is not responsible for a third party's vaccine mandate. *See Null v. FDA*, Civil Action No. 09-1924, 2009 WL 10744069, at *3 (D.D.C. Nov. 10, 2009) (rejecting argument that a New York vaccine mandate was fairly traceable to FDA's approval of a vaccine). The Sixth Circuit recently rejected a similarly attenuated theory of standing, observing that "[m]any cases . . . hold that a plaintiff failed to establish that an injury was traceable to a defendant when the injury would

[6] The declarations are also unclear as to whether, or when, the declarants would face discipline, including court martial. *Cf.* 10 U.S.C. §§ 822-24 (specifying persons authorized to convene courts martial); Meacham Decl., ECF No. 15 at 56 (limiting court-martial authority); Sweger Decl., ECF No. 15 at 180 (withholding court-martial authority).

arise only if some third party decided to take the action triggering the injury." *AAPS II*, 13 F.4th at 546 (citing cases); *see also Clapper*, 568 U.S. at 413 ("[W]e have been reluctant to endorse standing theories that require guesswork as to how independent decisionmakers will exercise their judgment."). Here, any injuries are due not to FDA's actions, but to a third party—the Department of Defense—independently requiring vaccination.

Moreover, some of the declarants' alleged injuries are not even fairly traceable to the Department of Defense mandate. For example, some declarants allege that they have faced "ridicule" or social pressure as a result of not getting the vaccine, or that they have been subject to unwanted COVID testing and mask mandates, or that commanders have kept them out of certain activities due to their unvaccinated status. *See, e.g.*, Craymer Decl. ¶¶ 8, 11; Eschmann Decl. ¶ 8, Hastriter Decl. ¶ 8; Nuss Decl. ¶¶ 5, 8, 12. But they offer no reason to think that any of these alleged injuries were caused by the Department of Defense's decision to require military members to get vaccinated, let alone FDA's decision to approve the Comirnaty vaccine.

3. For similar reasons, the declarants' alleged injuries are not likely to be redressed by the judicial relief sought. "An injury is redressable if a judicial decree can provide 'prospective relief' that will 'remove the harm.'" *Doe v. Dewine*, 910 F. 3d 842, 850 (6th Cir. 2018) (quoting *Warth v. Seldin*, 422 U.S. 490, 505 (1975)). "The relevant standard is likelihood—whether it is 'likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision.'" *Id.* (quoting *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC) Inc.*, 528 U.S. 167, 181 (2000)). And because "[r]edress is

sought *through* the court, but *from* the defendant," *id.* (citation omitted), redressability is harder to establish "where the prospective benefit to the plaintiff depends on the actions of independent actors." *Id.* (quoting *Parsons v. U.S. Dep't of Justice*, 801 F.3d 701, 715 (6th Cir. 2015)).

It is entirely speculative whether the relief Plaintiffs request will redress the declarants' alleged injuries. Plaintiffs never explain how vacating the Comirnaty license will cure their alleged injury of being required to take *unlicensed* vaccines. Even if FDA had not licensed Comirnaty, the President could authorize the Department of Defense to mandate vaccines covered by EUAs. *See* 10 U.S.C. § 1107a;[7] *cf.* Memorandum Opinion for the Deputy Counsel to the President, Whether Section 564 for the Food, Drug, and Cosmetic Act Prohibits Entities from Requiring the Use of a Vaccine Subject to an Emergency Use Authorization (July 6, 2021), https://www.justice.gov/olc/file/1415446/download. Indeed, it is a matter of public record subject to judicial notice that, before FDA approved the Comirnaty vaccine, the Secretary of Defense stated that he "will seek the President's approval to make the vaccines mandatory no later than mid-September, or immediately upon [FDA's] licensure, *whichever* comes first." Memorandum for All Department of Defense Employees (Aug. 9, 2021) (emphasis

[7] *Doe v. Rumsfeld*, 297 F. Supp. 2d 119 (D.D.C. 2003) is inapposite because an EUA-authorized vaccine is not an investigational new drug. 21 U.S.C. § 360bbb-3(k); *see also* 10 U.S.C. § 1107a(c) (providing that the statute at issue in *Doe* "shall not apply" to an EUA-authorized vaccine). Even if Plaintiffs were to get all the relief they seek—vacatur of both the Comirnaty license and the Pfizer-BioNTech EUA—*Doe* confirms that the President may mandate the use of an investigational vaccine by issuing a waiver. *See Doe*, 297 F. Supp. 2d at 125.

added), https://media.defense.gov/2021/ Aug/09 /2002826254/-1/-1/0/MESSAGE-TO-THE-FORCE-MEMO-VACCINE.PDF. Moreover, Plaintiffs' request to vacate the Pfizer-BioNTech EUA is unlikely to redress the declarants' "injuries" because EUAs "are exempt from review under the APA," *AAPS I*, 2020 WL 5745974, at *3, and other EUA-authorized vaccines could still be mandated.[8]

B. CHD does not seek to protect interests germane to its purpose.

CHD also fails to meet the second requirement of associational standing: it has not pleaded or shown that the declarants' interests are germane to CHD's purpose. CHD does not describe its purpose in its filings in this Court, or explain how the declarants' interests are related to that purpose. That failure to plead this essential element of associational standing is sufficient by itself to warrant dismissal.

Moreover, the Court may take judicial notice that CHD's website states that the organization's purpose is "to end childhood health epidemics by working aggressively to eliminate harmful exposures, hold those responsible accountable, and to establish safeguards so this never happens again." Children's Health Defense, http://www.childrenshealthdefense.org (accessed October 13, 2021). The declarants are not children or guardians of children seeking to protect the rights of children—they are

[8] Although Plaintiffs allege in passing that EUAs for the Moderna and Johnson & Johnson vaccines are also unlawful, Am. Compl. ¶¶ 30, 42, they do not request that this Court invalidate those EUAs. *See* Am. Compl., at 12 (asking the Court "[t]o vacate and remand the FDA's decision to license Pfizer's Comirnaty vaccine and to extend its Pfizer-BioNTech Emergency Use Authorization"). Furthermore, those EUAs—like the Pfizer EUA—are unreviewable. *See infra* II.A.

adult members of the United States military seeking to protect their own alleged interests in not being required to obtain a COVID-19 vaccination. Those interests—not the interests of children—are what CHD purportedly seeks to protect in this suit. Because those interests are unrelated to CHD's organizational purpose of preventing childhood epidemics, CHD fails to satisfy this second requirement of associational standing.

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For the foregoing reasons, Plaintiffs have failed to set forth plausible factual allegations that establish their standing, and the Court should dismiss the case.

II. Plaintiffs Have No Valid Claims For Relief.

If the Court does not dismiss for lack of jurisdiction, it should dismiss for failure to state a claim and deny Plaintiffs' motion for a preliminary injunction. Although the Amended Complaint expressly identifies only one "cause of action"—a challenge to the Comirnaty license as "arbitrary and capricious"—it includes various assertions that both the license and the EUA are unlawful. *See, e.g.*, Am. Compl. ¶¶ 26, 27, 38, 48. But Plaintiffs' scattershot claims contain no plausible basis for relief. Because Plaintiffs do not identify any relevant factors that FDA allegedly failed to consider and do not identify any arbitrary or capricious action on the part of FDA, they have failed to state a claim under the APA. *See Jomaa v. United States*, 940 F.3d 291, 299 (6th Cir. 2019); *see also Mann Constr., Inc. v. Internal Revenue Serv.*, 495 F. Supp. 3d 556, 574 (E.D. Mich. 2020).

A. Plaintiffs' challenge to the EUA is unreviewable.

Much of Plaintiffs' Amended Complaint challenges the lawfulness of FDA's decision to maintain the Pfizer-BioNTech EUA. In particular, Plaintiffs contend that FDA acted unlawfully in declining to revoke the EUA when FDA approved the license for the Comirnaty vaccine, Am. Compl. ¶¶ 27-31, 42-43, 48, and that the EUA must be set aside as arbitrary and capricious, *id.* ¶¶ 38-39, 43-45, 49, 55. These contentions are wrong. *See infra* II.B and II.C. But they fail to afford a basis for relief for a reason that is even more fundamental: the APA does not authorize review of FDA's decision to maintain an EUA.

Agency action is unreviewable under the APA when it "is committed to agency discretion by law." 5 U.S.C. § 701(a)(2). The EUA statute expressly states that FDA's "[a]ctions under the authority of this section . . . are committed to agency discretion." 21 U.S.C. § 360bbb-3(i). Following this plain statutory language, the Sixth Circuit has held that "emergency-use authorizations are exempt from review under the APA." *AAPS I*, 2020 WL 5745974, at *3 (citing 5 U.S.C. § 701(a)(2); 21 U.S.C. § 360bbb-3(i)). Thus, under binding circuit precedent, an APA challenge to FDA's issuance of an EUA is not available, and this Court should therefore dismiss Plaintiffs' challenges to the EUA.[9]

[9] Defendants assume, in line with recent Sixth Circuit precedent, that 5 U.S.C. § 701(a)(2)'s limitation on judicial review is not jurisdictional. *See Barrios Garcia v. U.S. Dep't of Homeland Sec.*, 2021 WL 4144034, at *4, *6, *11 (6th Cir. Sept. 13, 2021). *But see, e.g.*, *Stew Farm, Ltd. v. Nat. Res. Conserv. Serv.*, 767 F. 3d 554, 560 n.3 (6th Cir. 2014) (describing § 701(a)(2) as a "jurisdictional bar"); *Madison-Hughes v. Shalala*, 80 F. 3d 1121, 1127 (6th Cir. 1996) (same). Whether jurisdictional or not, 5 U.S.C. § 701(a)(2) requires dismissal here.

B. FDA's decision to maintain the EUA comports with § 360bbb-3.

Even if it were reviewable, Plaintiffs' assertion that FDA violated the EUA statute by maintaining the EUA is unfounded. Noting that one of the criteria for *issuing* an EUA for a product is that FDA find that "there is no adequate, approved, and available alternative" to the product, 21 U.S.C. § 360bbb-3(c)(3); Am. Compl. ¶ 28, Plaintiffs allege that "[o]nce FDA approved and licensed Pfizer's Comirnaty vaccine, there was no further basis for the FDA to *preserve* the EUA status for the Pfizer-BioNTech vaccine …." Am. Compl. ¶ 29 (emphasis added). That conclusion is unwarranted for two reasons.

First, even though FDA approved the Comirnaty vaccine, the agency found that there remains "no adequate, approved, *and available* alternative" to the EUA vaccines for reasons including (1) "there is not sufficient approved vaccine available for distribution to [the 16-year-old and older] population in its entirety," and (2) "there are no products that are approved to prevent COVID-19 in individuals age 12 through 15, or that are approved to provide an additional dose to the immunocompromised population described in th[e] EUA]." Am. Compl., Ex. 3, at 5 n.9. Plaintiffs themselves repeatedly emphasize that the Comirnaty vaccine is not an available alternative to EUA-authorized vaccines. *See, e.g.*, Am. Compl. ¶ 41, 47 (describing the Comirnaty vaccine as "unavailable" and referring to the Comirnaty vaccine's "lack of availability"); ECF No. 14, at 6 (describing the Comirnaty vaccine as "largely unavailable"). Nonetheless, they call this finding "specious" with an unsupported, conclusory assertion that Pfizer could make its Comirnaty vaccine "available" by changing the labeling on its EUA-authorized vaccine. Am. Compl. ¶ 46. But they plead no facts to show that Pfizer could change its

labeling, or that doing so would make the licensed vaccine "available" for the entire vaccine-eligible population.

Second, even if the Comirnaty vaccine were an "adequate, approved, and available alternative," nothing in 21 U.S.C. § 360bbb-3 *requires* FDA to *revoke* existing EUAs simply because the conditions that gave rise to their issuance no longer apply. Indeed, the provision governing revocation of EUAs says that, if the criteria justifying the original issuance of an EUA "are no longer met," then FDA "*may* revise or revoke" the EUA. 21 U.S.C. § 360bbb-3(g)(2) (emphasis added). The verb "may" is ordinarily permissive, *see Old Life Ins. Co. of Am. v. Garcia*, 411 F.3d 605, 614-15 (6th Cir. 2005); *Goodman v. City Prods. Corp, Ben Franklin Div.*, 425 F.2d 702, 703 (6th Cir. 1970), particularly when the statute elsewhere uses the term "shall" to confer a mandatory duty. *Anderson v. Yungkau*, 329 U.S. 482, 485 (1947) ("[W]hen the same rule uses both 'may' and 'shall,' the normal inference is that each is used in its usual sense—the one act being permissive, and the other mandatory."); *see also* A. Scalia & B.A. Garner, *Reading Law: The Interpretation of Legal Texts* 112 (2012) ("The traditional, commonly repeated rule is that *shall* is mandatory and *may* is permissive.").

There is nothing to indicate that 21 U.S.C. § 360bbb-3(g)(2) departs from this ordinary meaning of "may." To the contrary, § 360bbb-3 consistently uses "may" as permissive and "shall" as mandatory. *Compare, e.g.*, 21 U.S.C. § 360bbb-3(a) (providing that the Secretary "may" issue an EUA) *and id.* § 360bbb-3(b)(1) (providing that the Secretary "may" declare a public emergency), *with, e.g., id.* § 360bbb-3(b)(3) (providing that the Secretary "shall" provide notice in advance of terminating a declaration) *and id.*

§ 360bbb-3(h)(1) (providing that the Secretary "shall" publish certain EUA actions in the Federal Register). Thus, even if the EUA were reviewable, Plaintiffs' challenge would fail.

C. Plaintiffs' remaining APA claims fail.

Beyond challenging the lawfulness of maintaining the EUA under § 360bbb-3, Plaintiffs allege that the EUA, the Comirnaty license, or both must be set aside as arbitrary and capricious because they somehow show a lack of reasoned decisionmaking. The APA's requirement of "reasoned decisionmaking" means that "agency action is lawful only if it rests 'on a consideration of the relevant factors.'" *Michigan v. E.P.A.*, 576 U.S. 743, 750 (2015) (citation omitted)). The "relevant factors" governing approval of a vaccine license are set forth in the Public Health Service Act: FDA "shall" approve an application for licensure on the basis of a demonstration that (1) "the biological product . . . is safe, pure, and potent," (2) "the facility in which the biological product is manufactured, process, packed, or held meets standards designed to assure that the biological product continues to be safe, pure, and potent," and (3) "the applicant (or other appropriate person) consents to the inspection of the facility." 42 U.S.C. § 262(a)(2)(C).

Here, Plaintiffs do not argue that FDA failed to consider any of these factors. Nor do they argue that FDA failed to consider any factor relevant to maintaining an EUA beyond their mistaken assertion that FDA must revoke the EUA because there is an "available" alternative. Instead, their main theory appears to be that FDA's licensure of the Comirnaty vaccine while maintaining the Pfizer-BioNTech EUA is a "bait-and-

switch" designed to give Pfizer both the "imprimatur of safety, effectiveness and legality" that comes with a license, and the limitation on liability that, they claim, comes only with an EUA. Am. Compl. ¶¶ 1-2, 39, 49. The premise of that theory is that the Public Readiness and Emergency Preparedness Act confers product liability immunity only for EUA-authorized vaccines, and not licensed ones. *See, e.g.*, Am. Compl. ¶ 2.

That premise is false: PREP Act immunity does not differ between COVID-19 vaccines that are licensed and those that are EUA-authorized. Rather, the PREP Act confers immunity on vaccine manufacturers for injuries stemming from the administration or use of any "covered countermeasure," except in cases of willful misconduct. 42 U.S.C. § 247d-6d(a), (d). The term "covered countermeasure" is expressly defined to include *both* (1) "a biological product . . . that is *authorized for emergency use*," *and* (2) a "qualified, pandemic or epidemic product," including "a biological product . . . that is *licensed* . . . to diagnose, mitigate, prevent, treat, or cure a pandemic or epidemic." *Id.* §§ 247d-6d(i)(1)(A), (1)(C), (7)(A) (emphases added). Both EUA-authorized and licensed COVID-19 vaccines are therefore subject to the PREP Act's limitation on liability.[10]

[10] The Secretary confirmed the eligibility of licensed and EUA-authorized vaccines to prevent or mitigate COVID-19 for the liability limitation in the *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19*, 85 Fed. Reg. 15198, 15202 (Mar. 17, 2020). The Declaration has been reissued many times since March 2020, most recently on September 14, 2021. *See* 86 Fed. Reg. 51160. None of the reissuances have affected the eligibility of either licensed or EUA-authorized vaccines for PREP Act limitations on liability and compensation under the Countermeasures Injury Compensation Program.

Plaintiffs also assert that the Comirnaty license must be set aside because FDA did not consult its advisory committee on whether to approve the license, and because the approval of the license has supposedly misled the public into believing that the Pfizer-BioNTech vaccine is licensed. Am. Compl. ¶¶ 23, 24. But FDA is not required to consult its advisory committee before acting on an application, *see* 21 C.F.R. § 14.171(a), and Plaintiffs identify no legal basis for their claim that alleged public confusion about the status of the Pfizer-BioNTech vaccine somehow invalidates the Comirnaty vaccine license.

At bottom, Plaintiffs are simply inventing novel requirements for FDA action under the guise of requiring "reasoned decisionmaking." Because they identify no relevant factor that the agency failed to consider, they fail to state a claim upon which relief may be granted.

III. Plaintiffs Fail To Satisfy The Preliminary Injunction Factors.

Even if this Court does not dismiss Plaintiffs' Amended Complaint, it should deny Plaintiffs' motion for a preliminary injunction. To begin with, Plaintiffs are not likely to succeed on the merits. To obtain a preliminary injunction, they must not only satisfy the *Twombly/Iqbal* pleading standard, but also show a "substantial likelihood" that they have standing and that they are entitled to relief. *Liberty Coins*, 748 F.3d at 689-

90; *Hargett*, 978 F.3d at 386; *Waskul*, 900 F.3d at 256 n.4. For the reasons set forth above, they have not carried that evidentiary burden.[11]

Nor do they make the required showing of irreparable harm. "[I]rreparable harm is an indispensable requirement for a preliminary injunction." *Michigan Educ. Ass'n Fam. Retired Staff Ass'n v. Michigan Educ. Ass'n*, 856 F. App'x 580, 586 (6th Cir. 2021) (internal quotation marks omitted). The Sixth Circuit has repeatedly made clear that a motion for a preliminary injunction should be denied if the plaintiff fails to establish "imminent" or "immediate" harm that is not "speculative." *See, e.g.*, *D.T. v. Sumner Cnty. Schs.*, 942 F.3d 324, 327 (6th Cir. 2019); *Abney v. Amgen, Inc.*, 443 F.3d 540, 552 (6th Cir. 2006). This Court already explained why Plaintiffs' original Complaint, motion for a preliminary injunction, and declaration failed to establish irreparable harm. *See* Order, ECF No. 10, at 3-5. And for the reasons explained *supra* I.A, their Amended Complaint and additional declarations establish no non-speculative injury. *Cf. Rhinehart v. Scutt*, 509 F. App'x 510, 514–15 (6th Cir. 2013) (finding no irreparable harm where health risks were speculative); *Abney*, 443 F.3d at 552 (similar). Because it remains uncertain whether CHD's members will be granted religious exemptions or which vaccines will be available to them, they have not established that those injuries would be irreparable. Moreover, CHD's members would not avoid any of the harms they allege by an

[11] In addition to failing to allege facts sufficient to show that their declarants have standing, Plaintiffs fail to provide any evidence to show that it is substantially likely that their declarants are members of CHD, as Plaintiffs allege in their Amended Complaint. Am. Compl. ¶ 18. As noted, *supra* note 6, none of the declarations state that the declarants are CHD members.

injunction that vacates the approval of the Comirnaty vaccine and the EUA authorization of the Pfizer-BioNTech vaccine, because they have not challenged the vaccine mandate and the Department of Defense could still implement its policy with other vaccines.

The balance of equities and the public interest also strongly favor FDA because Plaintiffs' requested relief would greatly harm the public. "Stemming the spread of COVID-19 is unquestionably a compelling interest." *Roman Cath. Diocese of Brooklyn v. Cuomo*, 141 S. Ct. 63, 67 (2020); *see also League of Indep. Fitness Facilities & Trainers, Inc. v. Whitmer*, 814 F. App'x 125, 129 (6th Cir. 2020) (describing the interest in combatting COVID-19 as "significant"). "The virus's effects on individual and community health is well documented." *Castillo v. Whitmer*, 823 F. App'x 413, 417 (6th Cir. 2020). COVID-19 has already infected nearly 44 million Americans, hospitalized over 3.1 million, and killed over 700,000. The vaccines have been shown to be effective at protecting people from COVID-19, especially severe illness and death, and at reducing the risk of spreading the virus that causes COVID-19. So far, over 217 million Americans have received at least one dose of a COVID-19 vaccine, and over the week ending October 7, 2021, an average of over 948,000 Americans per day received a vaccine.[12] There is a compelling public interest in ensuring that Americans who want to get vaccinated

[12] COVID Data Tracker Weekly Review: Interpretive Summary for Oct. 8, 2021, https://go.usa.gov/xFU9U; New Hospital Admissions, https://go.usa.gov/xFU9K (last updated Oct. 11, 2021); CDC, Benefits of Getting a COVID-19 Vaccine, https://go.usa.gov/xFPes (last updated Aug. 16, 2021); COVID-19 Vaccinations in the United States, https://go.usa.gov/xFQXD (posted Oct. 13, 2021).

continue to have access to the vaccine, and Plaintiffs' requested relief would make it more difficult for them to do so. The balance of equities and the public interest strongly oppose the requested injunction.

CONCLUSION

For the foregoing reasons, this Court should grant Defendants' Motion to Dismiss with prejudice and deny Plaintiffs' motion for a preliminary injunction as moot. In the alternative, this Court should deny Plaintiffs' motion for a preliminary injunction.

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Respectfully submitted,

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